

**REMARKS**

**I. Amendments to the Claims**

By the foregoing amendments to the claims, claims 1 and 7 have been amended to clarify that the percentage by weight of water is based on the total weight of the composition.

The amendments to the claims are supported throughout the application as filed, and have been made without prejudice or disclaimer to any subject matter canceled or recited herein. Applicants reserve the right to file one or more continuation and/or divisional applications directed to any canceled subject matter. No new matter has been added, and entry of the foregoing amendments of the above-identified application is respectfully requested.

**II. Response to Objection to the Drawings**

At pages 2-3 of the Office Action, the drawings have been objected to as allegedly being of insufficient quality to shown the improvements of the invention.

In response, Applicants submit herewith replacement drawings.

Accordingly, Applicants respectfully request reconsideration and withdrawal of this objection.

**III. Response to Claim Rejection Under 35 U.S.C. § 112, Second Paragraph**

At pages 3-4 of the Office Action, claims 7-9 and 13 have been rejected under 35 U.S.C. § 112, second paragraph, as allegedly being indefinite.

Specifically, the Examiner has stated that the percent values recited in the claims are incomplete because the claims do not specify the frame of reference used to measure the percent values.

To expedite prosecution in the present application, and not to acquiesce to the Examiner's rejection, the claims have been amended as described above. In particular, claim 7 has been amended to clarify that the percent values are "based on the total weight of the composition."

Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

#### **IV. Response to Claim Rejection Under 35 U.S.C. § 103**

At pages 4-5 of the Office Action, claims 7-9 and 13 have been rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over Wittwer et al. (U.S. Patent No. 4,738,724) in view of Ohwada et al. (J. Appl. Glycosci., 2003).

This rejection is respectfully traversed, for at least the following reasons.

The present claims are directed to a film-forming composition suitable for hard capsules, and method for preparing the same. More particularly, the present claims are directed to a film-forming composition for hard capsules, comprising 7-12% by weight of starch, 1-6% by weight of a plasticizer, 0.7-3% by weight of a gelling agent, and 79-91.3% by weight of water, and a method for preparing the same. The recited composition, and the hard capsules and films comprising the same, will be useful in various industrial fields, including pharmaceutical field and food field.

Contrary to the present claims, Ohwada et al. merely discloses that mungbean starch has an amylase content of 33.19%. In addition, Wittwer et al. discloses novel injection molded pharmaceutical capsules of starch having a cap member, body member, means for a plurality of compartments therein; and means for locking the cap and body members together to form a tamper-resistance connection. The capsule disclosed by Wittwer et al. is mainly composed of starch and water, and gelatin and/or plasticizer can also be added.

However, the composition recited in the present claims is different from that of Wittwer et al. As noted above, the present film-forming composition for hard capsules comprises 7-12% by weight of starch, 1-6% by weight of a plasticizer, 0.7-3% by weight of a gelling agent, and 79-91.3% by weight of water, whereas Wittwer et al. discloses 5 to 30 wt% of water (*see* line 44 to 48 of column 2, and line 43 to 45 of column 7), especially 7.5 (Example 9) to 21.6 (Example 8) wt% of water in the composition for hard capsules. The main component (about 80%) of Wittwer's capsule is starch or a mixture of starch and gelatin, not water.

In the compositions described in the present application, starch concentrations of more than 12 wt% resulted in problems. In particular, bubbles formed on the surfaces of the capsules and the films were not removed, or tailing at the end of the pins occurred during the dipping process of the hard capsules (*see* Example 1, and Figures 2B and 2C). In addition, although starch concentrations of less than 5 wt% did not result in surface bubbles, the film-

forming solution upon preparation of the capsules became too sloppy. Thus, a sufficient amount of the solution did not adhere to the pins, causing the thickness of the capsules obtained after drying to become too thin (less than 0.1 mm), thereby making it difficult to use the capsules as products.

Wittwer et al. does not teach or suggest the starch or the water concentrations recited in the present claims. In addition, Ohwada et al. does not remedy the serious deficiencies of Wittwer et al. Accordingly, Applicants respectfully request reconsideration and withdrawal of this rejection.

### **CONCLUSION**

In the event that there are any questions related to this response, or the application in general, it would be appreciated if the Examiner would telephone the undersigned attorney at the below-listed telephone number concerning such questions so that prosecution of this application may be expedited.

Respectfully submitted,

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Date: March 12, 2009

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